

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA**

<p>VINCENT W. FALA and JUDITH A. FALA, h/w 128 Lake Minisink Road East Dingman's Ferry, PA. 18328</p> <p style="text-align: center;">Plaintiffs,</p> <p style="text-align: center;">V.</p> <p>PENNSYLVANIA CVS PHARMACY, LLC c/o CVS Health Corporation One CVS Drive Woonsocket, RI 02895</p> <p style="text-align: center;">Defendant.</p>	<p>NO.:</p>
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PLAINTIFFS' CIVIL ACTION COMPLAINT

I. INTRODUCTION

1. This civil action involves claims of negligent administration of the adult Pneumococcal Vaccine Polyvalent (Pneumovax 23) on October 4, 2018, to plaintiff Vincent W. Fala at the CVS Pharmacy located at 5122 Milford Road, East Stroudsburg, Monroe County, Pennsylvania, Pennsylvania. After receiving the Pneumovax 23 vaccine, Mr. Fala suffered a severe and permanent injury to his right arm/shoulder requiring surgery, inpatient rehabilitation, future care and

therapy, and permanent loss of function.

II. JURISDICTION AND VENUE

2. This Court has jurisdiction based upon the diversity of the parties pursuant to 28 U.S.C. §1332 as the Plaintiffs are citizens of Pennsylvania and defendant Pennsylvania CVS Pharmacy, LLC (hereafter “CVS”) has as its sole member of the LLC CVS Pharmacy, Inc. which is a citizen of the state of Rhode Island. As a result, there is complete diversity of citizenship between the Plaintiff (Pennsylvania) and Defendant, Pennsylvania CVS Pharmacy, LLC (Rhode Island).

3. Venue is proper in the Middle District of Pennsylvania pursuant to 28 U.S.C. §1391(b)(1) and §1391(d) as CVS “resides” in the Middle District of Pennsylvania and a substantial part of the events and omissions giving rise to this lawsuit occurred in the Middle District of Pennsylvania, to wit, Monroe County, such that these contacts would be sufficient to subject CVS to personal jurisdiction if the Middle District of Pennsylvania were a separate state.

III. PARTIES

4. Plaintiff Vincent W. Fala, is an adult individual residing at 128 Lake Minisink Road East, Dingman’s Ferry, Pennsylvania. At all times material and relevant hereto Plaintiff Vincent W. Fala was, and remains, the husband of Plaintiff Judith A. Fala.

5. Plaintiff Judith A. Fala, is an adult individual residing at 128 Lake Minisink Road East, Dingman's Ferry, Pennsylvania. At all times material and relevant hereto Plaintiff Judith A. Fala was, and remains, the wife of Plaintiff Vincent W. Fala.

6. Defendant Pennsylvania CVS Pharmacy, LLC ("CVS") is a Pennsylvania limited liability company whose sole member is CVS Pharmacy, Inc., and has a principal place of business at One CVS Drive, Woonsocket, Rhode Island. Plaintiffs are asserting a professional liability claim against Defendant CVS.

7. Defendant CVS is liable for the negligent acts and/or omissions of its agents, authorized agents, ostensible agents, servants, workmen, and employees, as described herein, including, but not limited to, the following persons: Eric T. Wild, Martin Duclose, pharmacy technicians, and all persons (i) providing care and/or services (ii) related to the administration of the Pneumovax 23 vaccine (iii) to Vincent W. Fala (iv) on or about October 4, 2018 (v) at CVS Pharmacy located at 5122 Milford Road, East Stroudsburg, Pennsylvania.

IV. FACTS

8. On or about October 4, 2018, Plaintiffs Vincent W. Fala presented to the CVS pharmacy located at 5122 Milford Road, East Stroudsburg, Pennsylvania, to receive a pneumococcal vaccine.

9. Plaintiff Vincent W. Fala was prescribed the Pneumovax 23 vaccine by Martin Duclose, M.D. on October 4, 2018, while at the CVS.

10. The Pneumovax 23 vaccine, with National Drug Code 00006-4837-03, was then administered to plaintiff Vincent W. Fala in his right arm by an individual in a white coat believed to be a pharmacist working at the CVS whose name is Eric T. Wild.

11. The individual who administered the Pneumovax 23 vaccine to plaintiff Vincent W. Fala on October 4, 2018, at the CVS was an employee of defendant CVS Health Corporation.

12. On the evening of Thursday, October 4, 2018, Plaintiff Vincent W. Fala began having pain/discomfort in his right shoulder and phoned the CVS location in East Stroudsburg where he was administered the Pneumovax 23 vaccine.

13. He was transferred to a pharmacist who advised Mr. Fala that the shoulder pain was “normal” and that he should use ice.

14. On Sunday, October 7, 2018, plaintiff Vincent W. Fala was having increased and significant pain and discomfort in his right shoulder and so he presented back to the CVS Pharmacy where he was advised to take Tylenol and use ice.

15. On Monday, October 8, 2018, Vincent W. Fala presented to Main Line Health's Bryn Mawr Hospital with complaints of, *inter alia*, "right upper extremity pain and swelling."

16. Upon examination in the Emergency Department at Bryn Mawr Hospital, Mr. Fala was found to have swelling in his right deltoid and his acromio-clavicular joint was tender-to-palpation.

17. Upon examination in the Emergency Department at Bryn Mawr Hospital, Mr. Fala was found to have a fluid collection present in the area of his right shoulder.

18. Upon examination in the Emergency Department at Bryn Mawr Hospital, Mr. Fala was found to have "slight erythematous color of upper arm to clavicle."

19. Mr. Fala's Emergency Department laboratory data evidenced an elevated sedimentation rate and c-reactive protein rate.

20. While in the Emergency Department, Kevin B. Freedman, M.D., an orthopedic surgeon, was consulted.

21. While in the Emergency Department Dr. Freedman aspirated synovial fluid from Mr. Fala's right shoulder and that fluid was noted to be yellow and turbid and had a white blood cell count of 82,000 with 94% polys (neutrophils), and as such Mr. Fala was believed to have septic arthritis.

22. The aspirated synovial fluid was sent to be cultured, but ultimately revealed no growth of any bacteria/pathogen.

23. An MRI of the right shoulder with and without contrast showed, *inter alia*, a large amount of fluid in the subacromial/subdeltoid bursa with less pronounced fluid in the glenohumeral joint and extensive synovial thickening and enhancement that was concerning for post vaccination synovitis.

24. Mr. Fala was taken to the operating room on October 8, 2018, for incision and drainage of superficial and deep abscess and the diagnosis at the time was noted by Dr. Freedman to be right shoulder septic arthritis.

25. During the procedure, Dr. Freedman noted that there were pus collections and a “massive rotator cuff tear.”

26. Following a thorough irrigation and debridement, a drain was placed and Mr. Fala was taken from the operating room with a surgical drain, a plan for IV antibiotics, and consultation with an infection disease specialists.

27. During the surgical procedure on October 8, 2018, performed by Dr. Freedman, three (3) wound swabs were taken and sent for routine bacterial culture analysis

28. After forty-eight (48) hours, all three (3) wound swab cultures taken during the October 8, 2018, surgical procedure showed no growth of any bacteria/pathogen.

29. Mr. Fala remained hospitalized through October 13, 2018, at Bryn Mawr Hospital, at which time he was discharged to an inpatient rehabilitation facility for further care, management, and treatment.

30. On or about October 26, 2018, Mr. Fala followed-up with Bartholomew Bono, M.D., the Infectious Disease specialist who had seen Mr. Fala while he was in Bryn Mawr Hospital, and at that time Dr. Bono noted, *inter alia*, all of the cultures taken were sterile and that “[t]he other possible diagnosis is pseudoseptic arthritis of the shoulder, which has been reported following pneumococcal vaccination.”

31. The Defendant’s agent(s) and/or employee(s) and/or workmen and/or servant(s) directly and proximately caused Mr. Fala’s right shoulder injury by administering the Pneumovax 23 vaccine in an improper location.

32. The adult pneumococcal vaccine given to Mr. Fala on October 4, 2018, at the CVS in East Stroudsburg is not a “vaccine-related injury or death” under The National Childhood Vaccine Injury Act of 1986 because the vaccine given to Mr. Fala is not a covered vaccine on the Vaccine Injury Table.

33. Specifically, Mr. Fala was administered a pneumococcal *polysaccharide* vaccine, however, only pneumococcal *conjugate* vaccines are covered under the National Vaccine Injury Compensation Program. *See Zebrofsky*

v. Sec'y Health & Human Services, No.: 15-1084V at *2 (Fed. Cl. Spec. Mstr. September 28, 2017).

34. Therefore Mr. Fala is not required to prosecute his claim for a vaccine-related injury to the National Vaccine Injury Compensation Program and may bring this civil action directly.

35. The defendant's negligence and/or negligent acts and/or omissions of its agent(s) and/or employee(s) and/or workmen and/or servant(s), as set forth in detail below, increased the risk of harm and/or proximately caused Plaintiff Vincent M. Fala, to suffer the following injuries and/or harm:

- a. Pseudoseptic arthritis of the right shoulder;
- b. Aseptic inflammatory arthritis;
- c. Immune-mediated inflammatory reaction;
- d. Increased risk of infection;
- e. Lack of immunity/failed pneumococcal vaccine administration;
- f. Rotator cuff injury/tear(s);
- g. Shoulder injury resulting from vaccine administration ("SIRVA");
- h. Pain and suffering;
- i. Right shoulder injury;
- j. Musculoskeletal injuries;
- k. Causing and/or exacerbating an immune response;

- l. Loss of use and/or range of motion in the right shoulder joint;
- m. The need for inpatient hospitalization;
- n. The need for surgical intervention;
- o. The need for inpatient rehabilitation;
- p. The need for IV and oral antibiotic therapy;
- q. The need for future care and therapy;
- r. physical and emotional suffering;
- s. embarrassment and humiliation
- t. The need for additional surgical and/or medical procedures;
- u. The need for additional hospitalizations;
- v. injuries documented in his medical records;
- w. loss of life's pleasure;
- x. scarring and deformity;
- y. disfigurement;
- z. decreased mobility
- aa. past medical expenses, including by way of healthcare liens and/or
Medicare lien(s);
- bb. damage to his nerves and nervous system;
- cc. spousal loss of consortium; and

dd. The full measure of damages allowed under the law of the Commonwealth of Pennsylvania, including, but not limited to, the categories of expenses, contribution, support and/or services.

COUNT I – PROFESSIONAL NEGLIGENCE
VINCENT M. FALA AND JUDITH A. FALA V.
PENNSYLVANIA CVS PHARMACY, LLC

36. The paragraphs and allegations stated above are incorporated herein by reference and made a part hereof as if set forth in full.

37. Defendant CVS has held itself out to the public as a pharmacy and establishment wherein persons can obtain vaccines, including the pneumococcal vaccine received by Plaintiff Vincent M. Fala.

38. Defendant CVS acting through its agents, authorized agents, ostensible agents, servants, workmen, and employees, as described herein, failed to exercise due care and committed the following negligent acts and/or omissions:

- a. Improperly administering a vaccine to plaintiff;
- b. Injection of antigenic material into synovial tissues;
- c. Failure properly to train persons administering vaccines, specifically to plaintiff Vincent W. Fala;
- d. Injecting an intramuscular deltoid injection into the shoulder joint;

- e. Negligence *per se*, specifically including, but not limited to, failing to notify plaintiff's primary care physician in accordance with Section 9.2 of the Pennsylvania Pharmacy Act;
- f. Immune-mediated inflammatory reaction;
- g. Causing an intra-articular injection of the pneumovax 23 vaccine;
- h. Failing to recognize that plaintiff's injection was in an improper location;
- i. Failing properly to supervise the person administering the vaccine to plaintiff;
- j. Failing to follow package instructions/warnings with regard to the vaccine administered to plaintiff on October 4, 2018;
- k. Failing timely to recognize that plaintiff suffered an injury as a result of the improper vaccine administration;
- l. Failing timely to refer plaintiff to a physician and/or to an emergency department;
- m. Failing to examine the vaccine administration injection site upon his return to the CVS; and,
- n. Failing to follow policies and/or procedures and/or protocols regarding the site of injection for the pneumovax 23 vaccine

39. The carelessness and negligence of CVS, acting through its agents, authorized agents, ostensible agents, servants, workmen, and employees, as described herein as set forth above, increased the risk of harm and/or was a substantial factor and/or factual cause in causing the injuries and damages suffered by Plaintiffs, as set forth herein, and specifically as listed in ¶32 *supra*.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Pennsylvania CVS Pharmacy, LLC in an amount in excess of \$75,000, plus interest, costs, and delay damages.

COUNT II – CORPORATE NEGLIGENCE
VINCENT M. FALA AND JUDITH A. FALA V.
PENNSYLVANIA CVS PHARMACY, LLC

40. The paragraphs and allegations stated above are incorporated herein by reference and made a part hereof as if set forth in full.

41. Defendant CVS Health Corporation failed to provide reasonable healthcare services and the corporate negligence of Defendant CVS Health Corporation consisted of the following:

- a. A duty to use reasonable care in the maintenance of safe and adequate medical facilities for the administration of vaccines;
- b. A duty to select and retain only competent and adequately trained pharmacists and other persons who administer vaccines as described herein, including staff and/or employees;

- c. A duty to oversee all persons who administer vaccines within its walls and, in particular, the duty to oversee the pharmacists, technicians and others who provided the pneumovax 23 vaccine to plaintiff and/or administered the same to plaintiff;
- d. A duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patient; in particular, the duty to have rules and policies to:
 - i. ensure pharmacists and/or others administer vaccines at the proper site;
 - ii. ensure pharmacists and/or others administering vaccines fully comply with the Pennsylvania Pharmacy Act;
 - iii. ensure pharmacists and/or other staff are adequately trained with regard to vaccine administration procedures, proper injection site, and injection protocols;
 - iv. ensure pharmacists and/or other staff timely and/or properly respond to patient complaints;
 - v. ensure pharmacists and/or other staff timely and/or properly communicate with each other;

- vi. ensure pharmacists and/or other staff ensure proper monitoring of patients with post-vaccination complaints and/or signs and/or symptoms of serious medical conditions;
- vii. ensure that physicians prescribing the pneumovax 23 vaccine are made aware of post-vaccination patient complaints;
- viii. ensure that patient complaints are timely and appropriately assessed and responded to;
- ix. ensure that changes in a patient's condition are timely communicated to physicians, nurses, techs, aides, and/or other personnel responsible for patient medical care and/or treatment;
- x. ensure proper and timely communication/consultation of physicians, including prescribing physicians;
- xi. ensure proper training and supervision of the pharmacists and/or of staff administering vaccines and providing services and care to vaccine recipients.

42. The carelessness and negligence of CVS, acting through its agents, authorized agents, ostensible agents, servants, workmen, and employees, as described herein as set forth above, increased the risk of harm and/or was a substantial factor and/or factual cause in causing the injuries and damages suffered by Plaintiffs, as set forth herein, and specifically as listed in ¶32 *supra*.

43. Defendant CVS had actual or constructive knowledge of its failures as described above.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Pennsylvania CVS Pharmacy, LLC in an amount in excess of \$75,000, plus interest, costs, and delay damages.

COUNT III – VICARIOUS LIABILITY
VINCENT W. FALA AND JUDITH A. FALA V. PENNSYLVANIA CVS
PHARMACY, LLC

44. The paragraphs and allegations stated above are incorporated herein by reference and made a part hereof as if set forth in full.

45. Defendant CVS is liable for the negligent acts and/or omissions of its agents, authorized agents, ostensible agents, servants, workmen, and employees, as described herein, including, but not limited to, the following persons: Eric T. Wild, Martin Duclose, pharmacy technicians, and all persons (i) providing care and/or services (ii) related to the administration of the Pneumovax 23 vaccine (iii) to Vincent W. Fala (iv) on or about October 4, 2018 (v) at CVS Pharmacy located at 5122 Milford Road, East Stroudsburg, Pennsylvania.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Pennsylvania CVS Pharmacy, LLC in an amount in excess of \$75,000, plus interest, costs, and delay damages.

COUNT IV – SPOUSAL CONSORTIUM
JUDITH A. FALA V. PENNSYLVANIA CVS PHARMACY, LLC

46. The paragraphs and allegations stated above are incorporated herein by reference and made a part hereof as if set forth in full.

47. As a result of the negligence and carelessness as set forth herein, Plaintiff Judith A. Fala has suffered, and will continue to suffer, the loss of the services, support and consortium of her spouse, Plaintiff Vincent W. Fala.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Pennsylvania CVS Pharmacy, LLC in an amount in excess of \$75,000, plus interest, costs, and delay damages.

COUNT V – STRICT PRODUCTS LIABILITY
(RESTATEMENT 2d OF TORTS, §402A)
JUDITH A. FALA V. PENNSYLVANIA CVS PHARMACY, LLC

48. The paragraphs and allegations stated above are incorporated herein by reference and made a part hereof as if set forth in full.

49. As a result of the unreasonably dangerous and defective condition of the vaccine injectable, which CVS sold in the stream of commerce to Plaintiff, the defendant is strictly liable to the Plaintiff pursuant to §402A of the Restatement (Second) of Torts based on the following:

- (a) failing to properly and adequately design the vaccine injectable;
- (b) failing to properly and adequately manufacture the injectable;

- (c) failing to warn the Plaintiff of the dangerous nature of the vaccine injectable; and,
- (d) such other defects as shall be revealed in the course of discovery.

51. As a direct and proximate result of the foregoing acts/omissions leading to CVS' strict liability to Plaintiff, Plaintiff suffered the injuries and losses set forth above in ¶35.

Respectfully submitted,

By: /s/ Leon Aussprung and James E. Hockenberry

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